

Reply with Amendment and IDS
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REMARKS

Support for the Claim Amendments

Claim 18 is amended to recite a solution comprising macromers and *dispersed therein particles of a poorly water-soluble* anti-arrhythmic agent. Support for this amendment may be found in the specification at least at page 16 starting at line 16 (e.g., "The preferred anti-arrhythmic agents are poorly soluble in water"), to page 17, line 5; page 17, line 17 to page 18, line 2 (e.g., "dispersion and stabilization of the particles within the macromer solution..."). Applicants thus submit that this amendment does not introduce new matter. Accordingly, Applicants respectfully request that this amendment be entered.

Rejection of claims under 32 USC §103(a)

1. Claims 18-26 were rejected under 35 USC §103(c) as being unpatentable over Sawhney et al. (US5900245) in view of Levy et al. (US5387419). Applicants hereby amend the claims to more clearly and specifically recite the subject matter they regard as their invention. In particular, independent claim 18 now recites a solution comprising biodegradable, water-soluble macromers and *dispersed therein particles of a poorly water-soluble* anti-arrhythmic agent. Applicants respectfully submit that the present claims are patentable over the previously cited art.

Specifically, Sawhney does not teach or suggest compositions for the delivery of poorly water-soluble drugs from hydrogels, or from drugs in particulate form. Levy also does not teach or suggest compositions for the delivery of poorly water-soluble drugs from hydrogels, or from drugs in particulate form. The polymeric matrices in Levy are all hydrophobic matrices; they do not contain water-soluble macromers that form hydrogels. Levy constantly refers to his compositions as either films or substrates indicative that his matrices do not form gels.

Further, the cited references are not combinable as neither Sawhney, nor Levy teaches or suggests modification to their compositions to arrive at the presently claimed compositions. Rather, Levy teaches away from the present compositions as Levy teaches compositions for the delivery of *water soluble drugs* (see col. 6, line 67 to col. 7, line 2), where the release of the drug from the matrix is controlled by the hydrophobicity of the matrix, or only teaches delivery of

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poorly water-soluble drugs solubilized in hydrophobic matrices (see example 8, where amiodarone is solubilized in polar organic solvent and mixed into a polyurethane matrix in a soluble form then cast) - not in particulate form within water-soluble macromers that can form a hydrophilic matrix.

Even if combined the cited references do not teach the claimed invention as a whole as neither references teaches nor suggests the use of an anti-arrhythmic drug in a particulate form. Accordingly, Applicant respectfully submit that the present claims 18 to 26 are patentable over the previously cited references, and kindly request that the rejection be reconsidered in view of the present amendment and withdrawn.

2. Claims 18-26 were rejected under 35 USC §103(c) as being unpatentable over Purdue Research Foundation (WO02/16442). Applicants respectfully submit that the present claims are also patentable over Purdue.

Specifically, Purdue does not teach or suggest compositions for the delivery of poorly water-soluble drugs from hydrogels, or from drugs in particulate form. Also Purdue does not teach or suggest biodegradable macromers that would form a hydrogel capable of degrading in less than one month. Thus, Purdue does not teach or suggest the claimed invention as a whole. Accordingly, Applicants respectfully submit that the present claims 18 to 26 are also patentable over Purdue, and kindly request that the rejection be reconsidered in view of the present amendment and withdrawn.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement along with the list of cited references (Form 1449) and copies thereof are being filed after the mailing of the first Office Action on the merit under 37 CFR §1.97(c) along with the fee as set forth in §1.17(p). Applicants kindly request consideration of these references and return of the Form 1449 bearing the Examiner's initials.